Congress of the United States

Mashington, **BC** 20515 July 13, 2006

Dr. Andrew C. von Eschenbach Acting Commissioner Food and Drug Administration 5600 Fishers Lane Rockville, Maryland 20857

Dear Dr. von Eschenbach:

We would like to voice our opposition to the Food and Drug Administration's (FDA) continued delayed decision of Barr Laboratories' application for Plan B emergency contraception to be distributed over-the-counter (OTC).

After more than two years of delay, on August 26, 2005, the FDA again postponed its decision indefinitely to make Plan B emergency contraception available as an over-the-counter product to help women prevent unintended pregnancy.

Even while stating that "the available scientific data are sufficient to support the safe use of Plan B as an OTC product...for women who are 17 years of age or older," the FDA has postponed making a determination. The Agency has engaged in unnecessary delays to keep Plan B off of drug store shelves, where its accessibility will help women most.

Emergency contraception has been found to meet all the criteria for over-the-counter use: low-toxicity, no potential for overdose or addiction, no teratogenicity (is not harmful to an existing pregnancy), no need for medical screening, self-identification of the need, uniform dosage and no important drug interactions. We believe that in the FDA's continued delay in deciding on the application for EC over-the-counter status, science and safety have taken a back seat to politics.

Access to emergency contraception decreases the risk of unintended pregnancy. Whatever one's views on abortion, we all can recognize the importance of preventing unintended pregnancies.

Therefore, we ask you to render a decision on the status of Barr Laboratories' application to make EC available over-the-counter without further delay. Thank you for your attention to this important matter. We look forward to your prompt response.

Sincerely,

Christopher Mays

Member Congress

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Rob Simmons Member of Congress Judy Biggert
Member of Congress

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